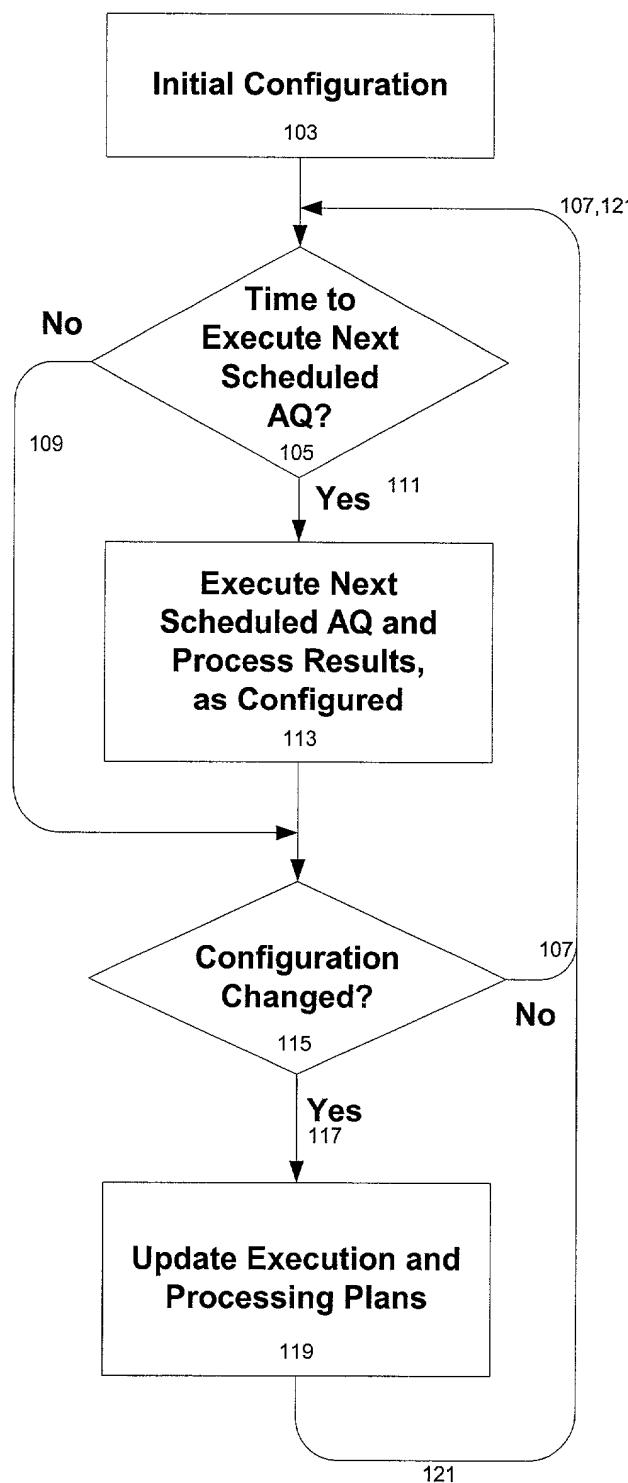


103: The **Initial Configuration** is used to define the execution and processing plans, including the following:

- **Query (search / trigger criteria)**
- **Admin Scope**
- **Admin Schedule**
- **Admin Activity**
- **Admin Query**

113: In this step the next scheduled **Admin Query**, is executed, querying the database, searching for records meeting the given **Admin Query** conditions, and processing all PRs in the **Result Set**.

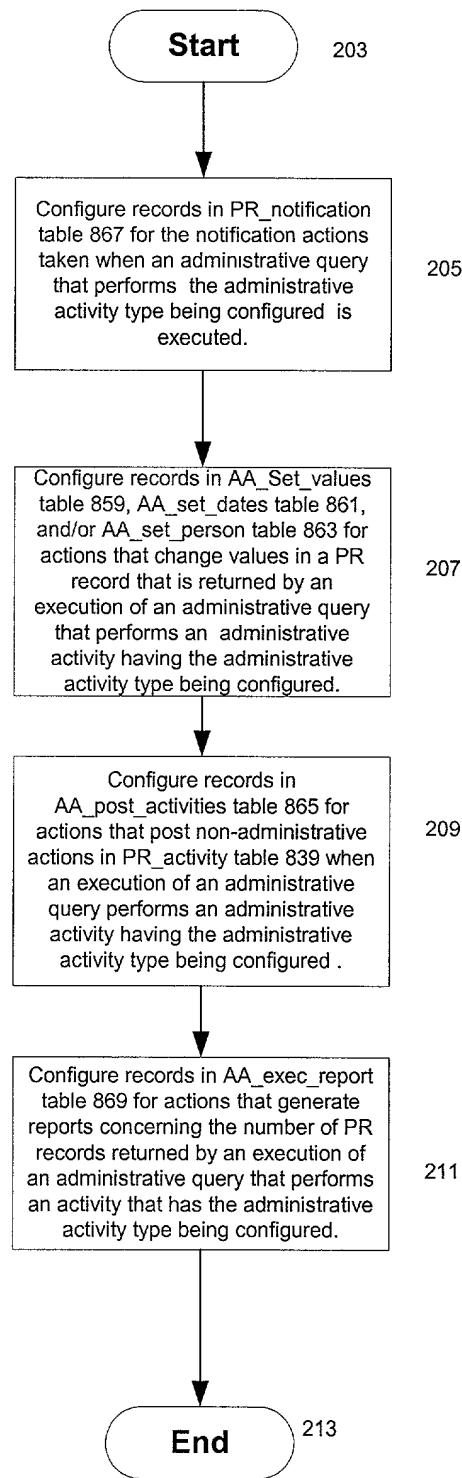
119: Upon detection of changes in the execution and, or the processing plans, the system adopts the new plans and is ready to continue with the next cycle



105: In this step the next Admin Query, if any, is executed, querying the database, searching for records meeting the given **Admin Query** conditions.

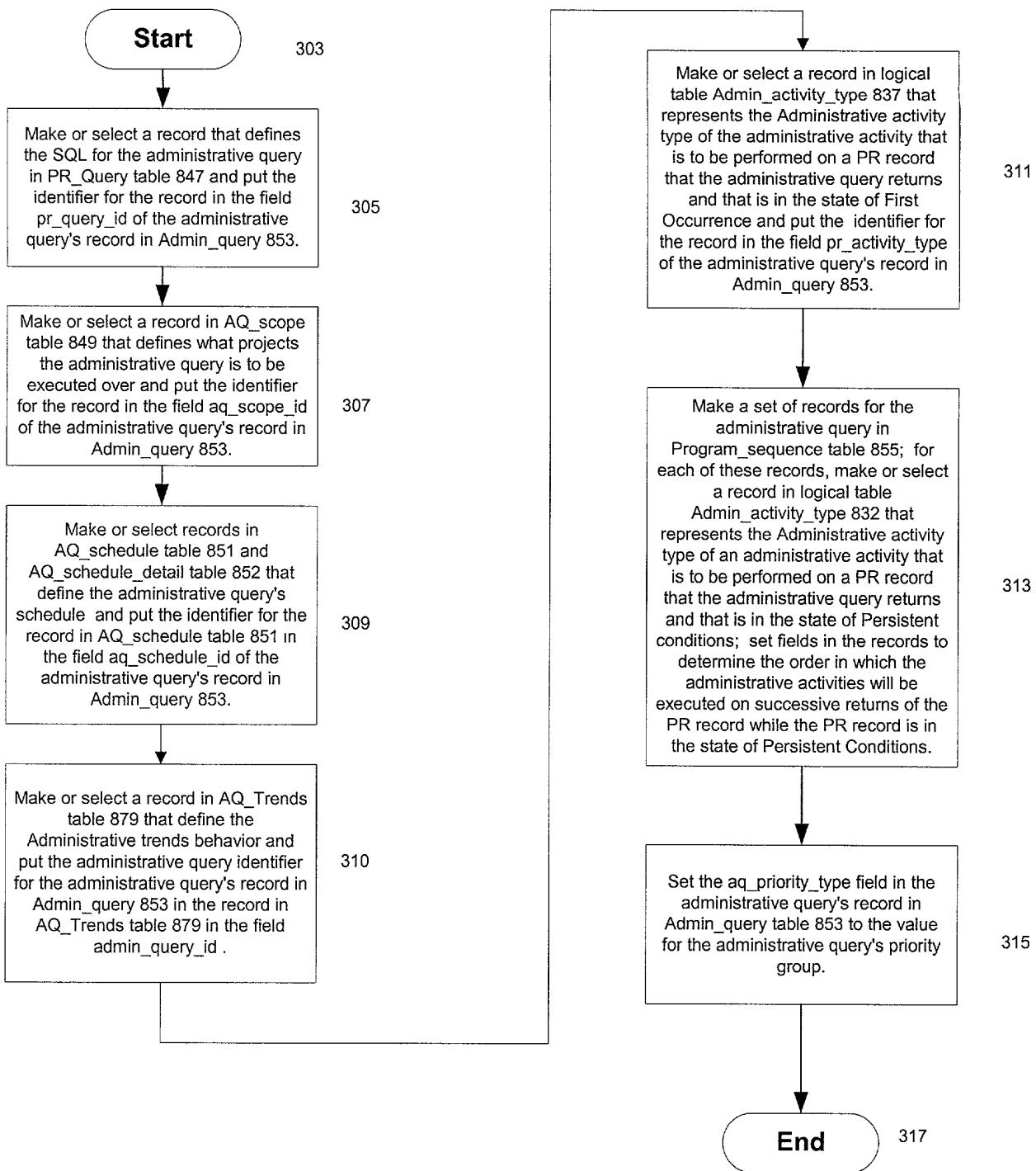
115: A periodical check for whether the current execution plan and process plan have changed, e.g.,

- Removal of exiting **AQs**.
- Changes in Admin Schedule.
- Changes in Admin Scope (adding or removing Projects, i.e., work areas).
- New Admin Activities.
- New Notification Rules.



201

**FIG. 2**



301

**FIG. 3**

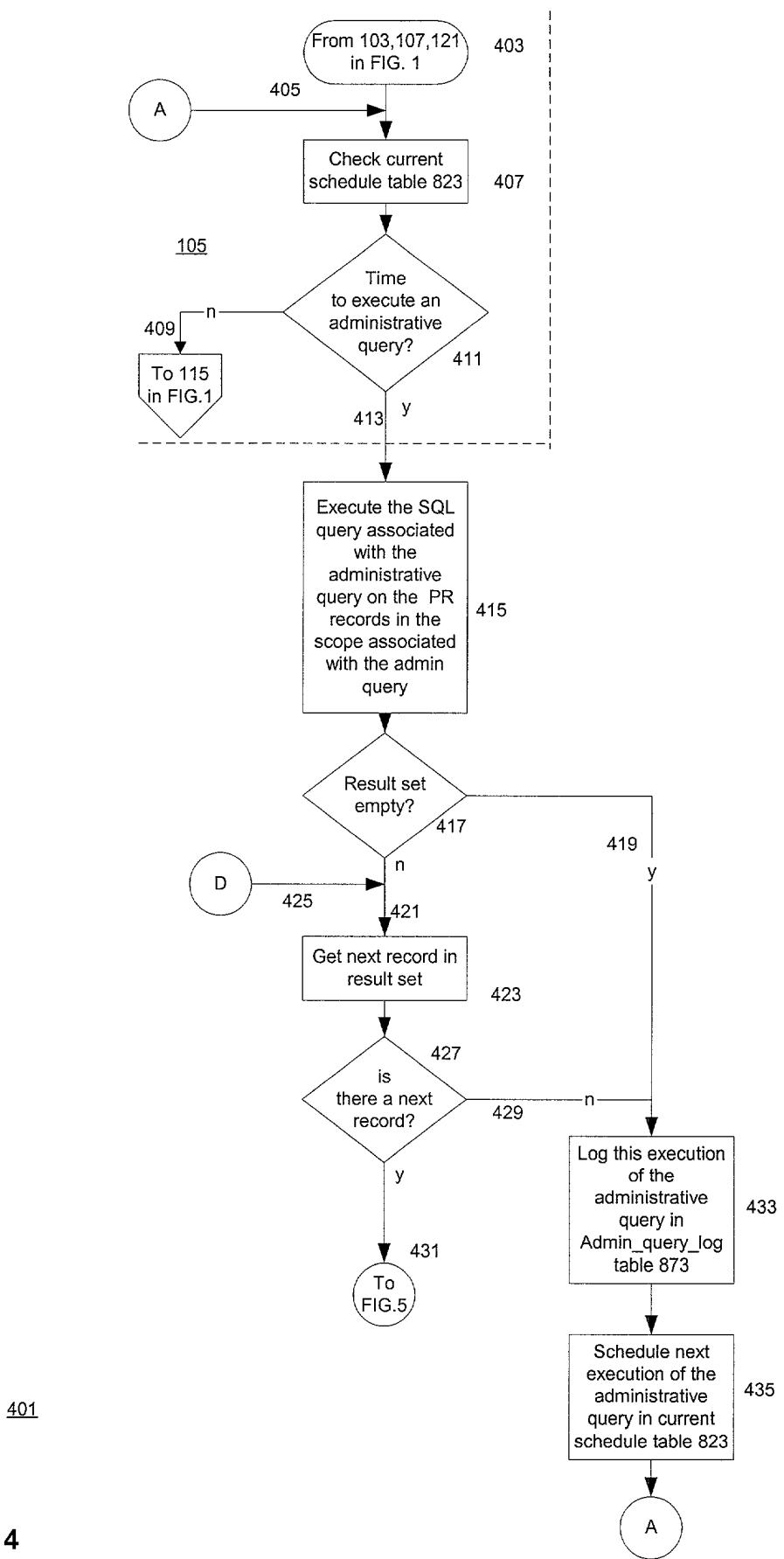


FIG. 4

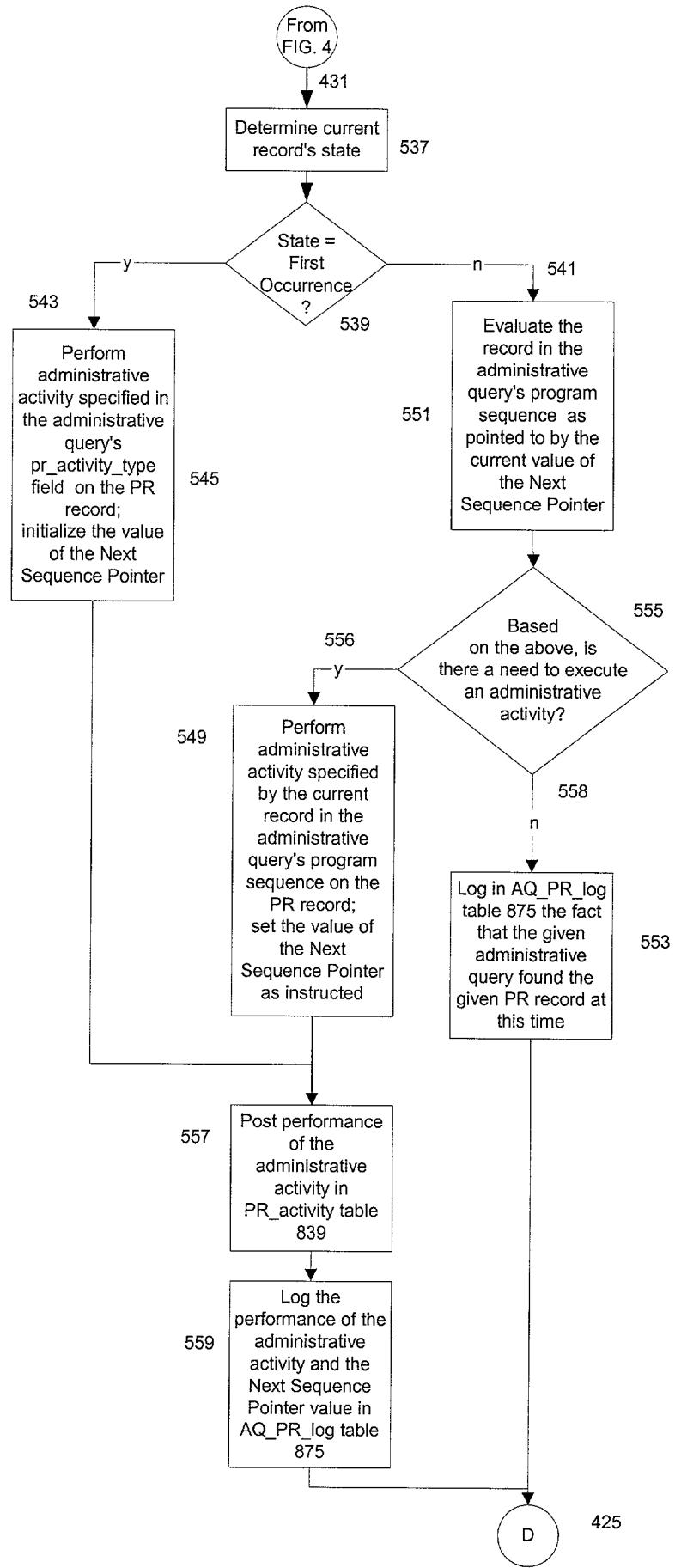


FIG. 5

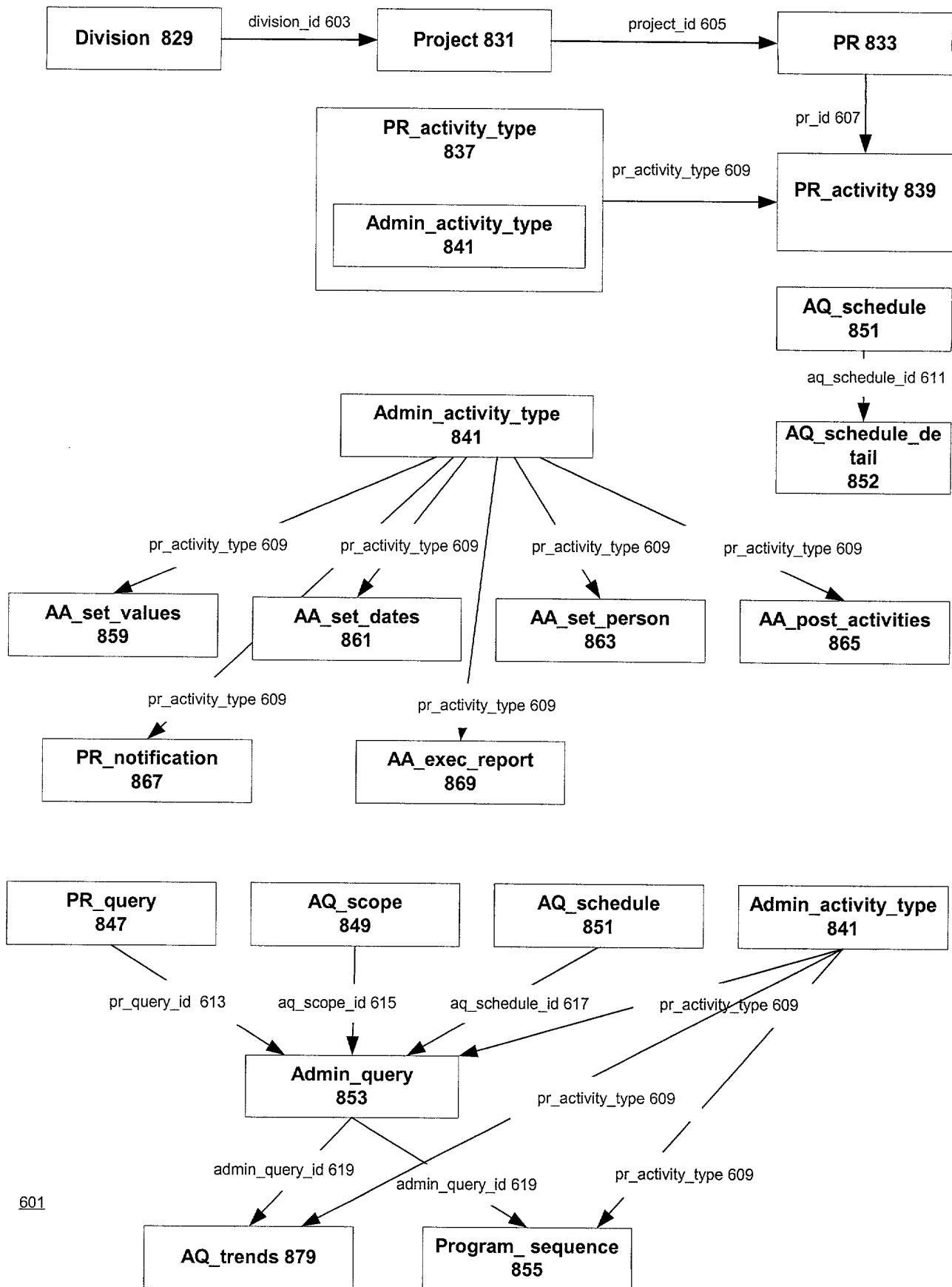
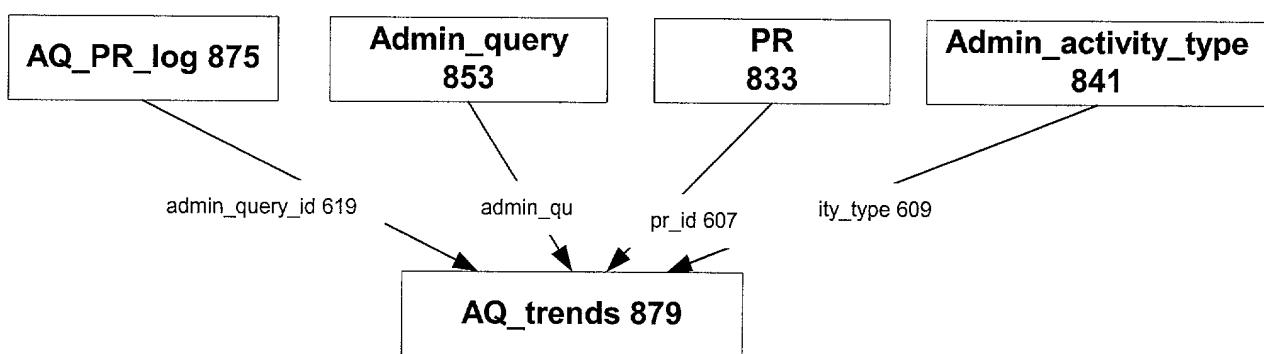
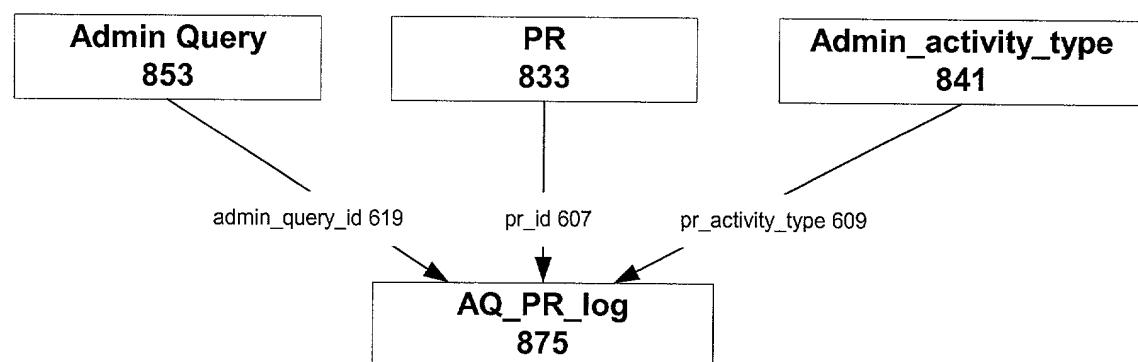
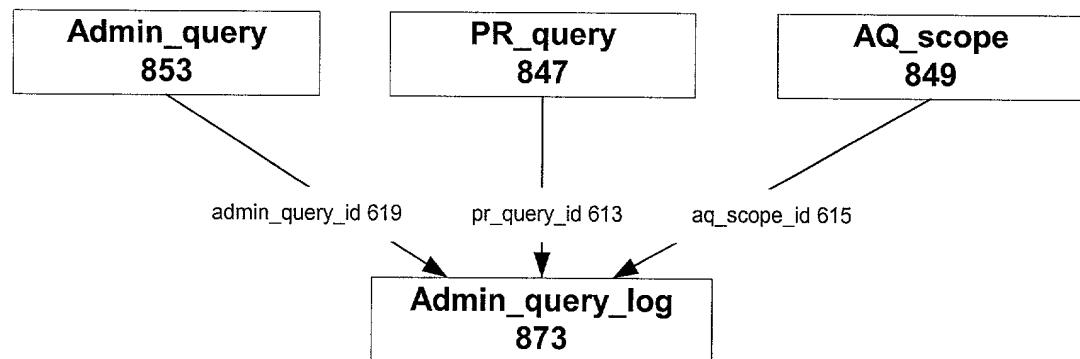


FIG. 6



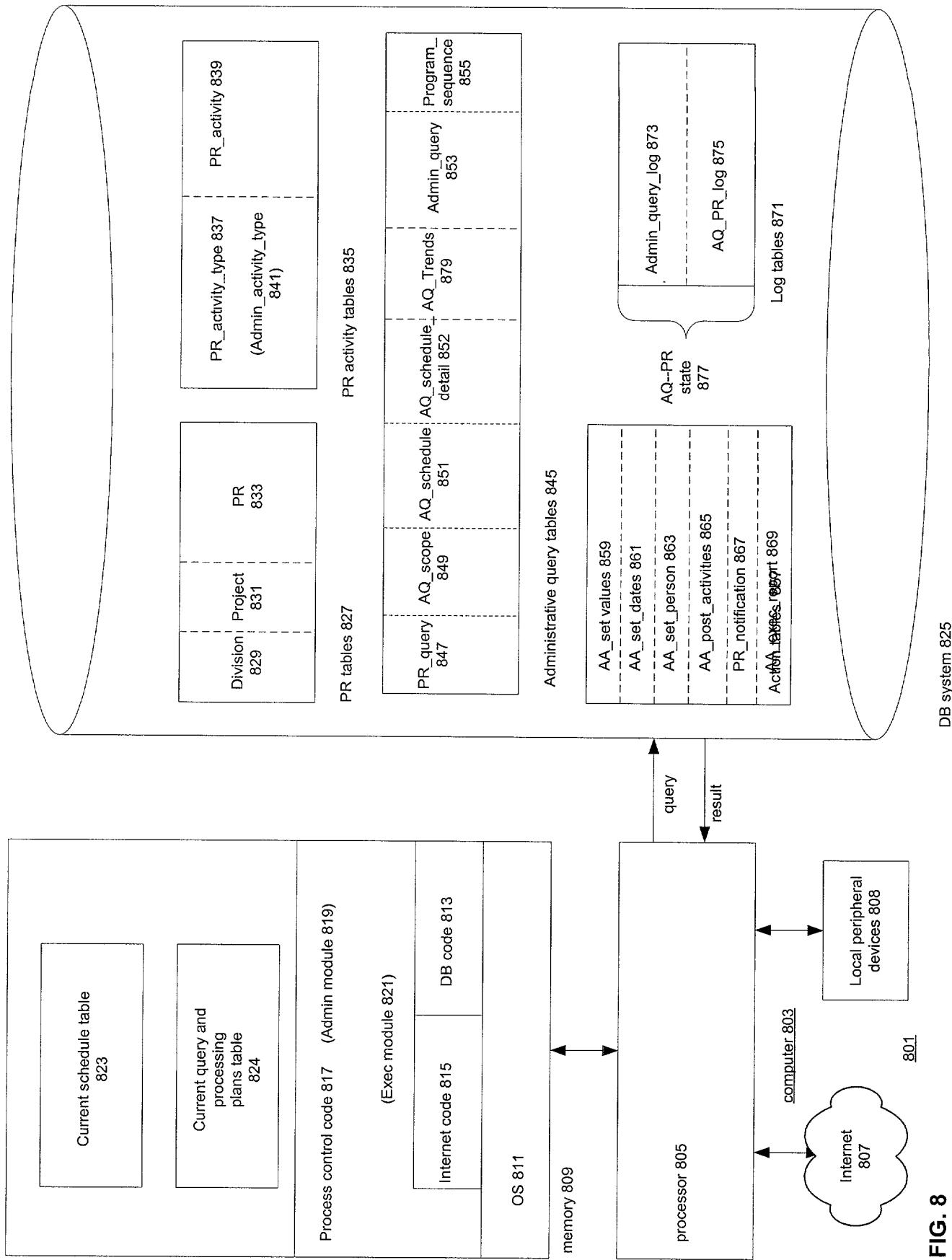


FIG. 8

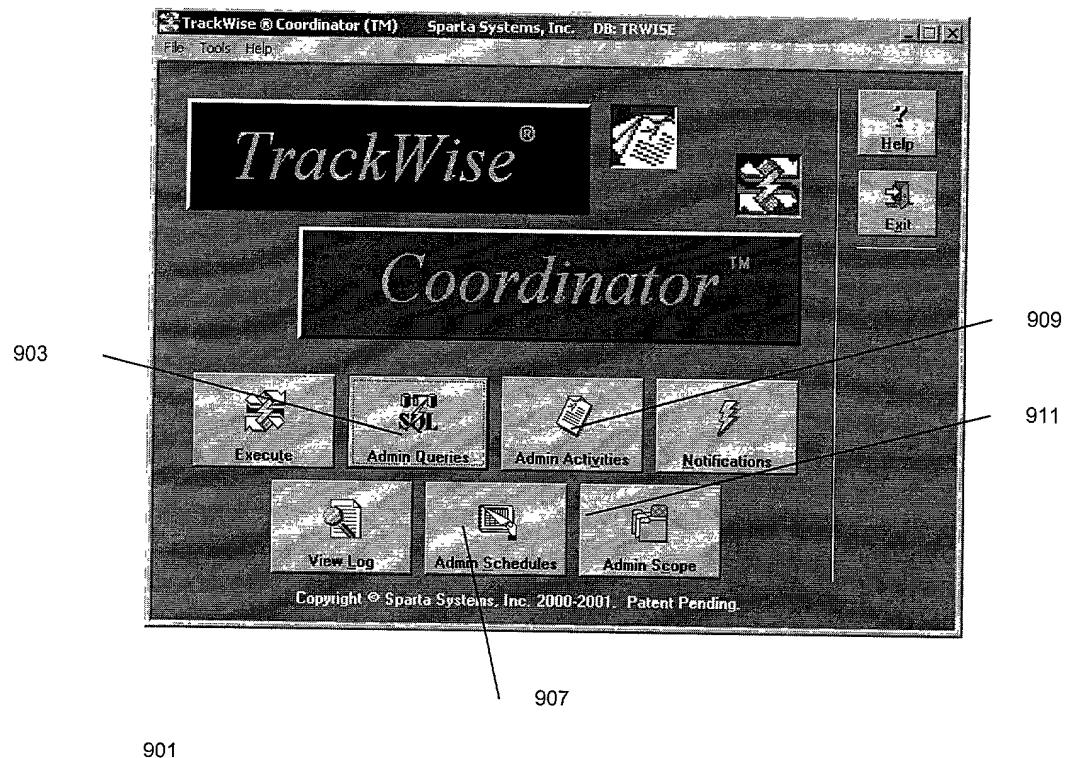
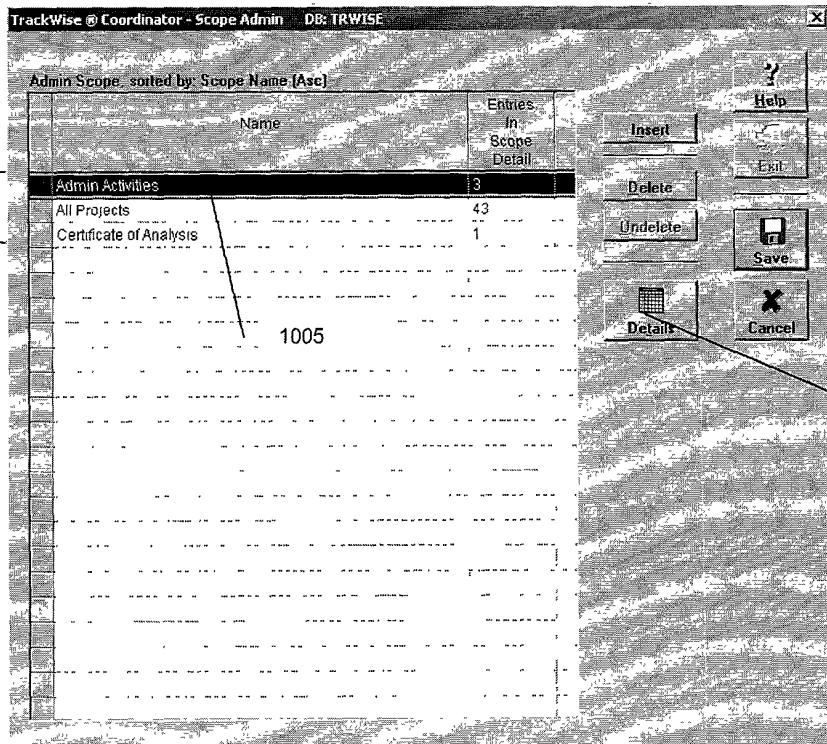


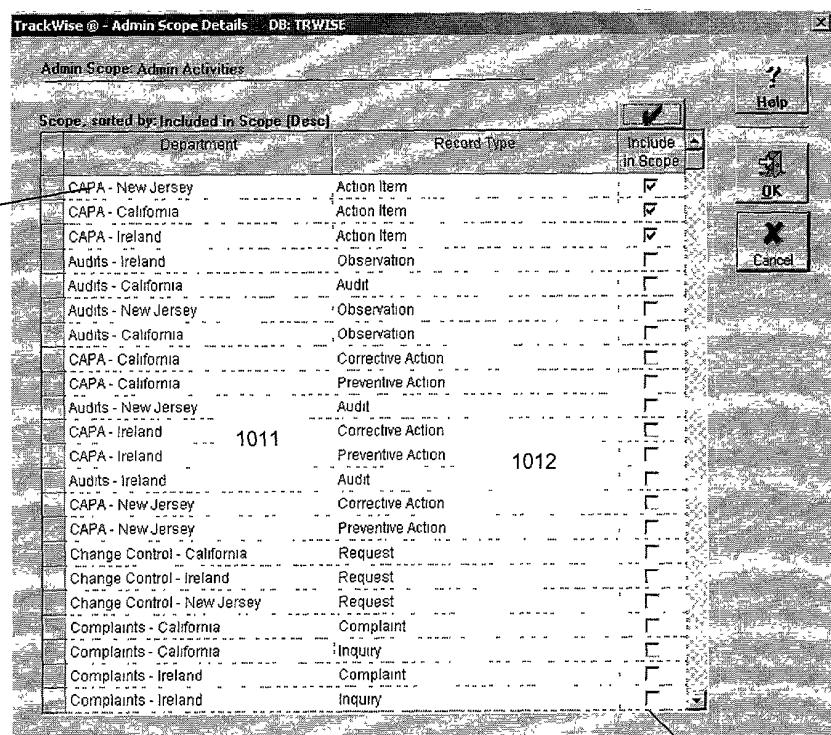
FIG. 9



1003

1005

1007



1010

1011

1012

1009

1013

FIG. 10

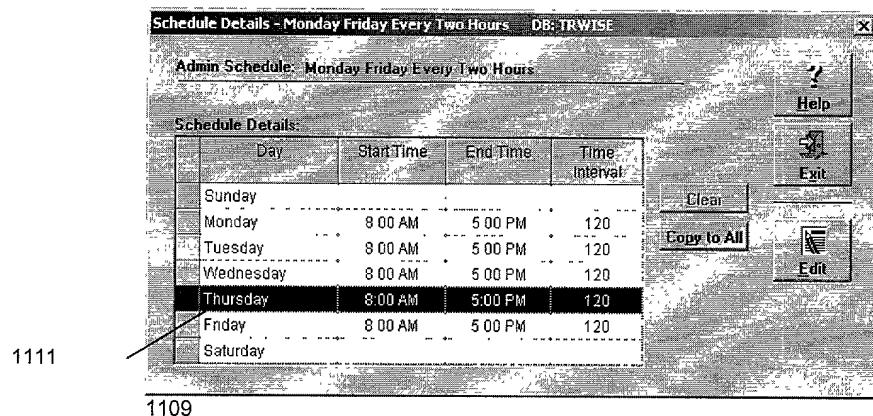
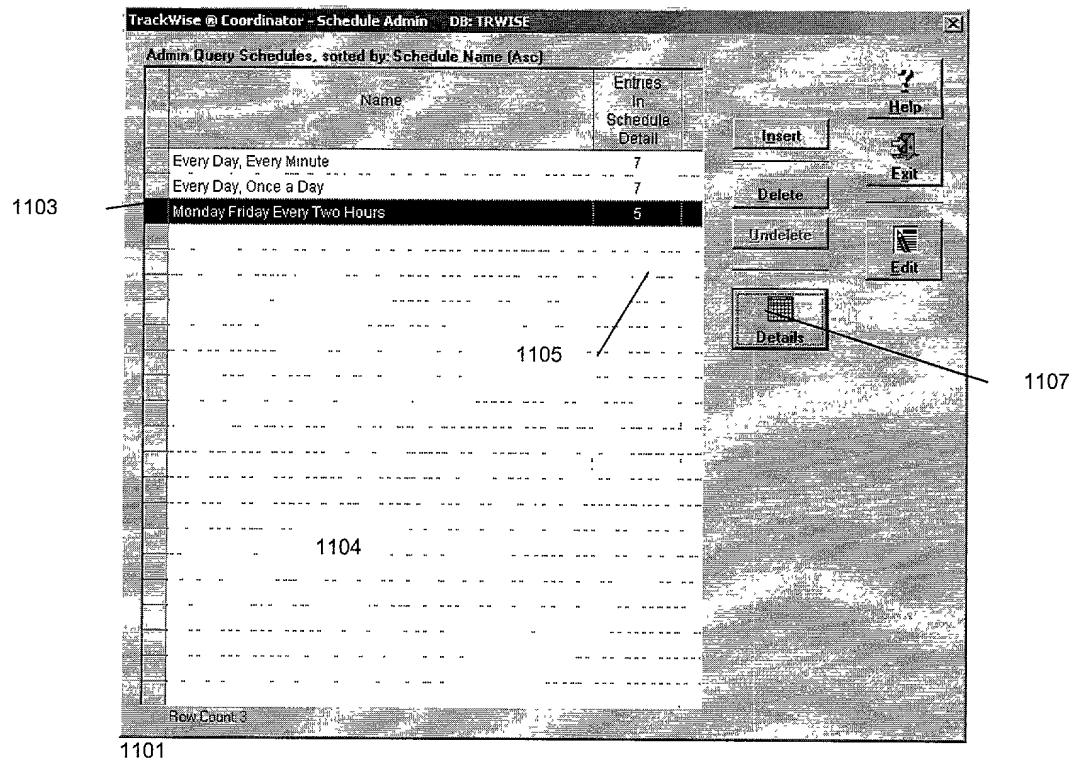


FIG. 11

1215

1217

1219

1221

1201

1207

1209

1203

1205

1211

1213

TrackWise Coordinator - Admin Activity Maintenance DB: TRWISE

Admin Activities Only All Activity Types

Help

Insert Exit

Delete Save

Undelete Cancel

Admin Activities, sorted by Admin Activity Name (Asc)

Admin Activity Name	Sets Values?	Sets Dates?	Sets Persons?	Posting Activities?
Assigned To Notification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Emergency Priority-Date Due Setting	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Priority Date Due Setting	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Normal Priority-Date Due Setting	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Post Begin Audit Activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
RNH 6279 Lower Limit Alert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RNH 6279 Upper Limit Alert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RNH 6280 Upper Limit Alert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RNH 6281 Upper Limit Alert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
RNH 6282 Upper Limit Alert	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Set Assigned To	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Set Priority to Emergency	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unassigned Record	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unassigned Record Notification	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

RowCount: 16

FIG. 12

Administration of Setting Selection Values

Admin Activity: Set Priority to Emergency

Set values, sorted by Field Name (Asc)

Field Name to Set	Field Type	Operation	Set Values
Additional Samples Tested?	Selection		
Affected SOP	Selection		
Assessment Method	Selection		
Assignable Cause	Multi-Selection		
Condition	Selection		
Disposition of Samples	Selection		
Final Disposition	Selection		
Governing SOP	Selection		
Impact	Selection		
Location	Selection		
Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection		
Proposed Disposition	Selection		
Type	Selection		

1302 1303 1305 1307 1309 1301

1306

Mfg Stage	Selection		
Phase	Selection		
Priority	Selection	Set	Emergency
Product Family	Selection		
Product(s)	Multi-Selection	Increment	1311
Proposed Disposition	Selection	Set	
Type	Selection	Clear	

1310

Selection Values DB: TR-WISE

Emergency
Low
Normal

1313

FIG 13

1402

Administration of Setting Date Values

Admin Activity: Assigned To: Notification

Field to Set	If Field is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
Audit Start Date							
Closed On							
Date Due							
Date Occurred							
Director Approval On							
Discovery Date							
Next Audit Date							
QA Approval On							
Received Questionnaire							
Response Due Date							
Sent Questionnaire							
Supervisor Approved On							

1403 1405 1411 1412

1401 1407 1409 1413

**Save** **Cancel**

1415

Administration of Setting Date Values

Admin Activity: Assigned To: Notification

Field to Set	If Field is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Analyst Approval On							
<input checked="" type="checkbox"/> Audit Start Date	Date Created						
Closed On	Date Created						
Date Due	Date Due						
Date Occurred	Date Occurred						
Director Approval On	Director Approval On						
Discovery Date	Discovery Date						
Next Audit Date	Next Audit Date						
QA Approval On	QA Approval On						
Received Questionnaire	Received Questionnaire						

1414 1417

1421

1419

1418

1424

Administration of Setting Date Values

Admin Activity: Assigned To: Notification

Field to Set	If Field is Blank, Base Field to Use	Add Value	Time Units	If Field Already Set, Base Field to Use	Add Value	Time Units	Business Days Rule
Closed On							
<input checked="" type="checkbox"/> Date Due	Date Created	30	Day(s)				Calendar
Date Occurred							
Director Approval On							
Discovery Date							
Next Audit Date							

1422 1423

1425

FIG. 14

1501

Administration of Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field is Blank, Person to Set	If Field is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set	Help
2nd Auditor					
Analyst Approval By					
Assigned To	Customer Support				
Closed By	Customer Support				
Contact	Developer				
Director Approval By	Project Leader				
Originator	Project Manager				
Person Notified	Quality Manager				

1513

1505 1507 1515 1509 1511

1503

1517

Administration of Setting Person Fields

Admin Activity: Set Assigned To

Field to Set	If Field is Blank, Person to Set	If Field is Blank, Person Role to Set	If Field Already Set, Person to Set	If Field Already Set, Person Role to Set	Help
2nd Auditor					
Analyst Approval By					
Assigned To			Benson, Harry		
Closed By					
Contact					

FIG. 15

1602

**Administration of Posting Activities**

**Admin Activity: Post Begin Audit Activity**

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
<b>Begin Audit</b>	<b>Perform</b>						
Begin Change Control	Schedule						
Begin Investigation	Perform						
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							
						1603	1609 1611
Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.							

1601

1604

1607

1613

**Administration of Posting Activities**

**Admin Activity: Post Begin Audit Activity**

Activity to Post	Posting Mode	Date Reference Field	Value	Time Units	Business Days Rule	Responsible by Function	Responsible by Name
Action Item(s) Complete							
All Responses Received							
*Analyst Approval							
*Approve Corrective Action							
*Approve Preventative Action							
<b>Begin Audit</b>	<b>Schedule</b>	<b>Current Date/Time</b>	<b>2</b>	<b>Day(s)</b>	<b>Calendar</b>	<b>Contact</b>	
Begin Change Control							
Begin Investigation							
*Change Control Cancelled							
Change Request							
*Close							
*Close - Defer							
*Close - Reject							
Comments							
Commitment Initiated							
Complete							
Complete Commitment							
Complete Correspondence							
						1614	1615
Note: Color-coded Activity Types Require Electronic Signature and can therefore be posted as Scheduled only.							

FIG. 16

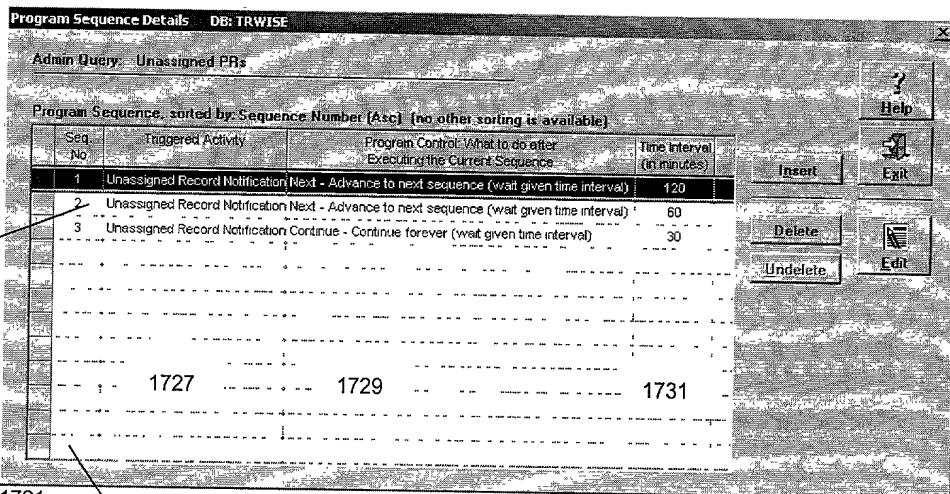
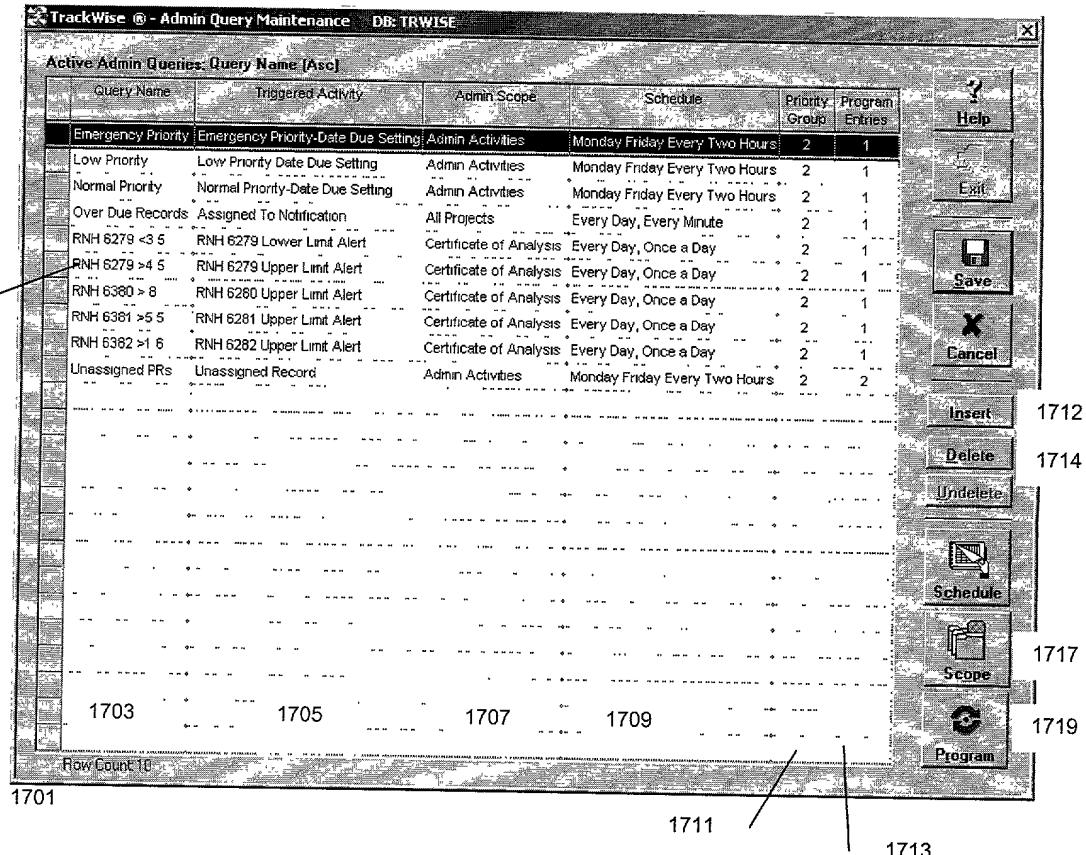
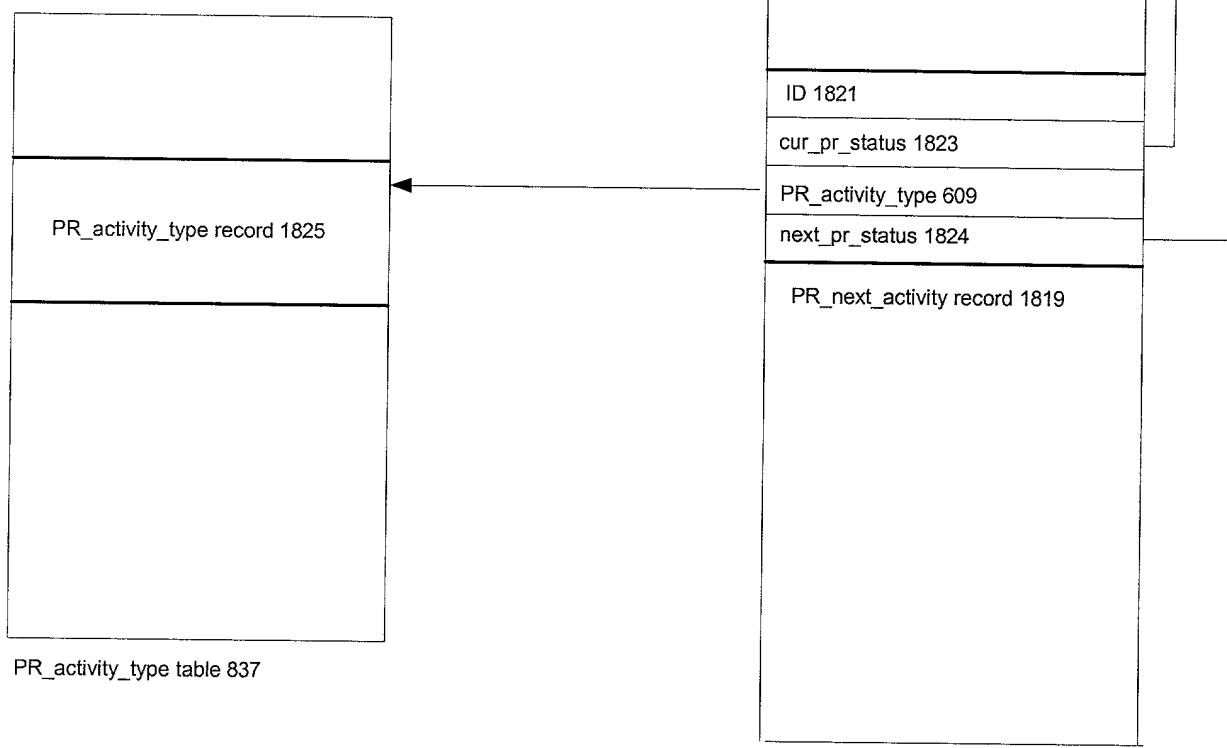
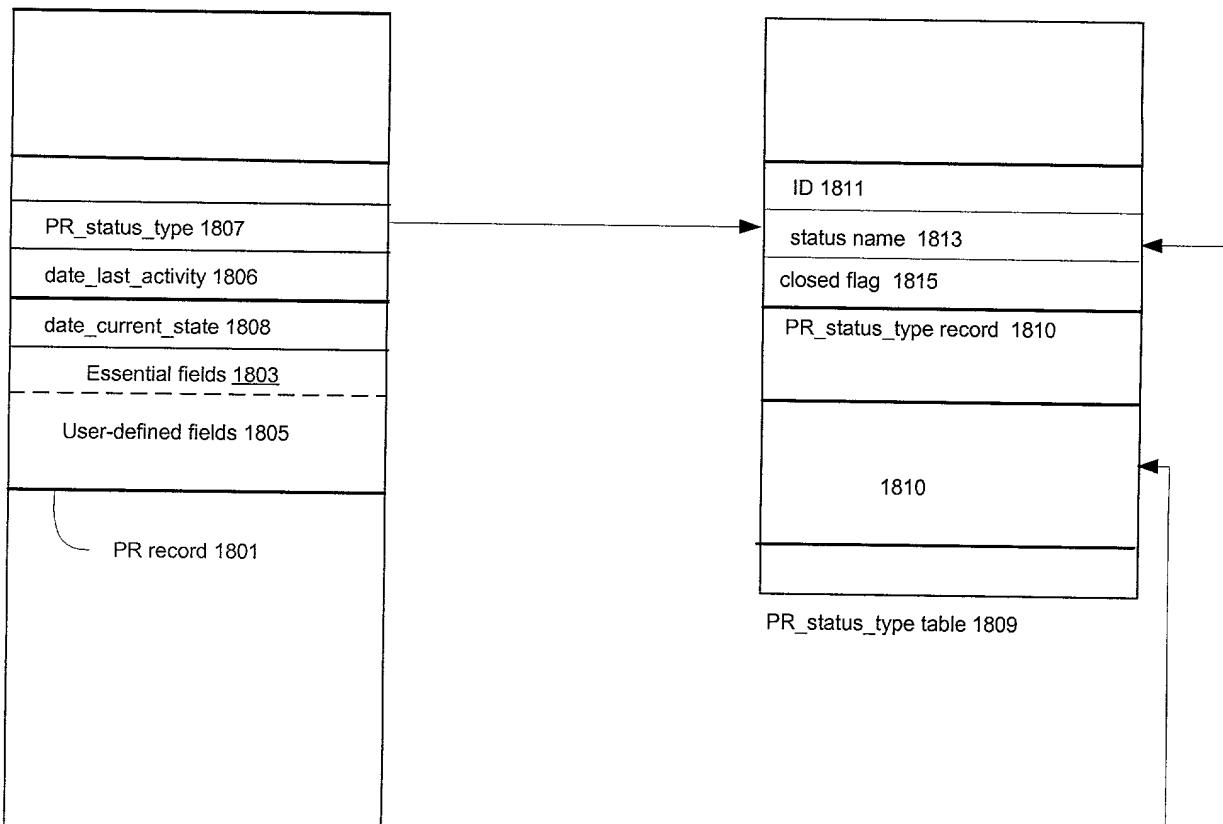


FIG. 17



**FIG. 18 Prior Art**

**Posting NEW Activity: <Approve Cor Act>**

REQ #: 1037	hhhh	1902	Customer:
CAPA Function / Project: Corrective Actions / CA		Entity: Spartan Pharmaceuticals	
Assigned To:	1905	1907	?
REQ State: Initiated	Help		
Activity Type: Approve Corrective Action 1903		Date/Time Scheduled: 12/01/2001 10:00 AM	Date/Time Performed: Today
Next State: Approved - Awaiting Action		Clear	1915
Person Responsible for this Activity: Ran J. Flam		Enter person's (Firstname Lastname)	Save
Participants	Notification	1909	Find
Activity Short Description: 1911			
Activity Summary and FlexFields (click open to select):			
Activity Summary: Ran, please approve the corrective action plan		Key Words:	
ADD Mode: Posting a NEW activity. Enter ALL necessary Data and <Save> when Done.			

1901

**FIG. 19**

TrackWise® - Activity Type Administration DB: TESTBASE

Search by Letter:  Sorted by: Name (Asc)

Activity Type	2009	Can Schedule	Min Participants	Can Edit All Data	Can Edit Summary Only
Activity A	Activity A	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Activity B	Activity B	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Activity C	Activity C	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Additional Work	Additional Work	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Approve Closed - No Action	Approve Closed - N	<input checked="" type="checkbox"/>	1	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Approve Work	Approve Work	<input type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Back to Initiated	Back to Initiated	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Back to Work In Progress	Back to WIP	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Begin Work	Begin Work	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Call Vendor	Call Vendor	<input checked="" type="checkbox"/>	0	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Row Count: 59

When Selected Activity is Performed:

Require Electronic

Require a person to be responsible for this Activity

Require summary

Set Date/Time UDF with Date Performed:

2019

Date/Time Approved

Schedule the Following Activity:

2023

Set Person UDF with the Person that Performed the Activity:

2021

The Approver

Number of Days After Date Performed:

2025

Summary Prompt    Completed Prompt    Scheduled Prompt    (120 ch's max)

2001

FIG. 20